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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/782,087

02/19/2004

Stephen T. Foley

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MEDTRONIC, INC.
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EXAMINER

HOLMES, REX R

ART UNIT

PAPER NUMBER

3762

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/782,087	Applicant(s) FOLEY, STEPHEN T.	
	Examiner REX HOLMES	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-31 and 33-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-31 and 33-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. This action is made final as it is a supplemental action addressing all of the claims that were filed on 12/10/07 in the amended claims.

Response to Arguments

2. Applicant's arguments filed 6/16/08 have been fully considered but they are not persuasive. The applicant argues that Bourgeois fails to disclose stimulating to disrupt normal activity. The examiner respectfully disagrees. Bourgeois shows that it stimulates to disrupt normal activity as shown in Figure 7.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 34 is rejected as it is dependent from a non-existent claim.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-5, 7-9, 27-29, 31, and 33-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Bourgeois (U.S. Pat. 6,216,039).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

7. Regarding claims 1, 27, 29, 33-36, Bourgeois discloses a system for gastric stimulation that utilizes a plurality of sensing electrodes (5) and a plurality of stimulating electrodes (4) placed in the stomach for sensing intrinsic activity (e.g. Fig. 1).

Bourgeois further discloses that it classifies the intrinsic activity as normal or abnormal and then stimulates the stomach with different stimulation parameters based on the classification (e.g. Fig. 7, see steps 7-8 and 7-14 which determine if normal waves are occurring and if so provides stimulation therapy at step 7-9). If the rate is outside of normal it resets the loop and withholds stimulation (Fig. 7).

8. Regarding claim 2, Bourgeois discloses that one end of the plurality of leads connect to the stimulator and the other end extends into the stomach wall and is positioned in the stomach (e.g. Fig. 1).

9. Regarding claim 3, Bourgeois discloses that the stimulation and sensing electrodes are positionable in different locations of the stomach wall (e.g. Fig. 1).

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10. Regarding claim 4, Bourgeois discloses that the device has a telemetry unit that communicates with an external programmer (e.g. Fig. 11).
11. Regarding claim 5, the system contains a programmable processor (e.g. 30).
12. Regarding claim 7, the system senses an interval, amplitude and duration of the sensed intrinsic activity (e.g. Col. 4, l. 37 to Col. 5, l. 13).
13. Regarding claim 8, the system communicates between the sensing electrodes and the stimulator to identify the frequency spectrum of the sensed gastric activity (e.g. Col. 4, ll. 37-55; Col. 6, ll. 6-27).
14. Regarding claims 9 and 31, the system discloses that it analyzes the sensed activity and determines if it is a slow wave or a peristaltic wave (e.g. Col. 7, l. 66 to Col. 8, l. 3).
15. Regarding claim 28, the stimulation channel is programmed to stimulate the stomach and inherently stimulate the nerves of the stomach (Fig. 1).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Applicant has provided evidence in this file showing that the invention was owned by, or subject to an obligation of assignment to, the same entity as Bourgeois at the time this invention was made, or was subject to a joint research agreement at the time this invention was made. However, reference Bourgeois additionally qualifies as prior

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art under another subsection of 35 U.S.C. 102, and therefore, is not disqualified as prior art under 35 U.S.C. 103(c).

Applicant may overcome the applied art either by a showing under 37 CFR 1.132 that the invention disclosed therein was derived from the invention of this application, and is therefore, not the invention "by another," or by antedating the applied art under 37 CFR 1.131.

18. Claims 6, 11-18 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bourgeois as applied to claims 1 and 7 above, and further in view of Gordon (U.S. Pat. 6,895,278).

19. Bourgeois discloses a gastrointestinal stimulation device as described in detail above, and further discloses that the stimulator is triggered on classified events and the stimulation is delivered to the stomach in the areas where the intrinsic activity was sensed (e.g. Figs. 1-2, 7). Bourgeois further discloses that the electrodes are spaced spatially throughout the stomach (Fig. 1). Bourgeois further discloses that the stimulation is delivered with a temporal offset that can be determined by the controller, or be programmed by a user (e.g. Col. 8, ll. 29-39). Bourgeois further discloses that the device can be setup for monopolar or bipolar stimulation (e.g. Col. 3, ll. 48-60).

20. Bourgeois further discloses that when the output pulse is to be delivered, its amplitude, pulse width, frequencies, and duration can be programmed and controlled by the controller (e.g. Col. 7, ll. 21-28). Bourgeois discloses that the pulse amplitudes, pulse durations, pulse periods, and relative pulse phasing among the electrodes can be

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controlled to stimulate the organ. (Col. 7, ll. 11-15). However, Bourgeois does not teach a power conservation condition or a way to save sensed data.

21. Gordon teaches a power conservation condition that takes into account the time of day and in the absence of a triggering activity (Col. 2, ll. 62-67 and Col. 3, ll. 1-5).

Gordon further discloses that the controller contains an internal storage device and the data can be telemetered using an inductive coupling methodology or radio communication methodology (Col. 15, ll. 1-9; Col. 10, ll. 44-58).

22. Regarding Claims 6 and 11-18, It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the gastrointestinal stimulation device of Bourgeois with the power conservation of Gordon in order to provide the predictable results of increasing the life of the stimulation device, increasing the life of the battery, and to increase the overall quality of life of the patient.

23. Regarding claim 30, Bourgeois discloses the claimed device including memory, but fails to disclose that the device maintains a history of predecessor events.

However, Gordon teaches a device that contains memory for storing the stimulation data so that it can be reviewed later to help provide better stimulation (Col. 10, l. 59 to Col. 11, l. 17; Claims 6, 8, 14 and 32). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the gastrointestinal stimulation device of Bourgeois with the memory storage of Gordon in order to provide the predictable result of a history of stimulation events for review to provide improved stimulation in the future.

Allowable Subject Matter

24. Claims 19-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REX HOLMES whose telephone number is (571)272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. H./
Examiner, Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762